

Application No. 10/631,228
Amendment dated April 14, 2008
Reply to Office action of February 12, 2008

REMARKS/ARGUMENT

Description of Claims

Claims 1, 3-5, 7-14, 16-29, 31-37 are pending.

Applicant respectfully requests reconsideration in view of the remarks presented below.

Rejections under 35 U.S.C. §112

Claims 10, 18, and 28 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants traverse for at least the following reasons.

In the Final Rejection on page 2, the Examiner alleges that “there is no teaching that any or all of these fluids are of the type to physically entrap an impurity without dissolving the impurity.” This statement is incorrect. On page 8, lines 19-20 of the specification, it is disclosed as an example that “low molecular weight components (i.e., molecules having less than 1000 daltons) can be removed by being suspended by water.” Water is listed as one of the possible components in claims 10 and 18, and water can be used as a component in claim 28. Thus, Applicants have demonstrated that at least one of these fluids is of the type to physically entrap an impurity without dissolving the impurity.

Further, definitions of “solvent” and “non-solvent” are given on page 8. The type of impurity will influence the solvent choice based on the “solvent” and “non-solvent” criteria given on page 8. Therefore, the Applicants have reasonably conveyed to one skilled in the relevant art that they had possession of the claimed invention.

Reconsideration and withdrawal of the §112 rejections of claims 10, 18, and 28 are respectfully requested.

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Rejections under 35 U.S.C. §103(a)

1. Claims 31-33 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Publication 2004/0063663 (“Buchanan”), U.S. Patent 5,762,944 (“Inoue”), and U.S. Patent 5,756,659 (“Hughes”).

Independent claim 31 requires “introducing a first fluid … acting as a solvent for the impurity” and “introducing a second fluid … acting as a non-solvent for the impurity.” Applicant submits that the cited references, individually and when combined, fail to teach or suggest this limitation. The Examiner stated that it would have been obvious “to have used any combination of solvents, including the use of a solvent together with a non-solvent … because Hughes teaches that more than one fluid can be used.” Applicants respectfully disagree.

Applicants have identified two approaches to removing impurities from a polymer: by dissolving the impurity and by entrapping the impurity without dissolving the impurity (specification page 8, lines 4-10), the latter approach capable of removing low molecular weight components (specification page 8, lines 19-20). None of the cited references recognize a distinction between using solvents and non-solvents and none teach or suggest the desirability of using a combination of a solvent and a non-solvent to remove impurities from a polymer. Hughes merely provides that “the stripping agent(s) should have a vapor pressure sufficient to either be a gas or form gas bubbles...” (col. 6:64-66). The Examiner has not provided any line of reasoning as to why a person of ordinary skill in the art, at the time of the invention, would introduce “a first fluid … acting as a solvent for the impurity” and “a second fluid … acting as a non-solvent for the impurity,” as required by claim 31. Instead, the Examiner has impermissibly applied an “obvious to try” rationale where none of the cited references gives an indication of what parameter is critical (i.e., solubility). See MPEP 2145, X, B. Accordingly, Applicants respectfully request removal of this rejection.

Claims 32 and 33 depend from claim 31 and are patentably allowable over Buchanan, Inoue, and Hughes for at least the same reasons as claim 31.

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2. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication 2004/0063663 (“Buchanan”), U.S. Patent 5,762,944 (“Inoue”), and U.S. Patent 5,756,659 (“Hughes”) as applied to claim 31 above, and further in view of U.S. Publication 2005/0106203 (Roorda et al.). Applicants traverse for at least the following reasons.

The Roorda et al. rejection under 35 U.S.C. 103(a) is based on prior art under 35 U.S.C. 102(e) because the publication date of Roorda et al. is May 19, 2005, which is after the filing date of the present application. In order to be disqualified as prior art under 35 U.S.C. 103(c), the subject matter which would otherwise be prior art to the claimed invention and the claimed invention must be commonly owned, or subject to an obligation of assignment to a same person, at the time the claimed invention was made or be subject to a joint research agreement at the time the invention was made. See MPEP § 706.02(l)

The present application 10/631,228 and US Publication 2005/0106203 were, at the time the invention of the present application was made, owned by Advanced Cardiovascular Systems, Inc., now Abbott Cardiovascular Systems Inc.

Applicants submit that this statement alone is sufficient evidence to disqualify Roorda et al. from being used in a rejection under 35 U.S.C. 103(a) against the claims of the present application.

Applicants respectfully request reconsideration and withdrawal of the rejection of claim 34.

3. Claims 1, 3-5, 8-10 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication 2004/0063663 (“Buchanan”), U.S. Patent 5,762,944 (“Inoue”), and U.S. Patent 5,756,659 (“Hughes”) and U.S. Patent 4,117,714 (Goodson et al.).

Claim 1 recites: “the fluid is of a type to physically entrap the impurity without dissolving the impurity.” Applicant respectfully submits that the cited references, individually and when combined, fail to teach or suggest this limitation of claim 1.

The Examiner stated that “Buchanan, Inoue, and Hughes do not explicitly teach that the fluid is a type to physically entrap the impurity without dissolving the impurity.” The Examiner further cites Goodson and states that Goodson teaches that “there are only a finite number of

identified, predictable potential solutions in the method of removing impurities.” Applicants respectfully submit that none of the portions of the Goodson reference cited by the Examiner, nor any other portions, teach the above statement. The cited portion of Goodson teaches that “the air 18 is scrubbed as it passes through and above the rotating film 20 and any impurities therein are dissolved or entrapped in the water film.” See (col. 3, lines 39-42). At most, this statement teaches that impurities may be removed from air by passing them through a film of water. It is an impermissible stretch to say that this statement generally teaches that there are only a finite number of predictable solutions for removing impurities.

Accordingly, the Examiner has provided no support or explanation as to why an organic solvent or water of Inoue must necessarily (1) physically entrap monomers and (2) would not dissolve the monomers. Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection.

4. Claims 13, 16-18 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan, Inoue, Hughes and Goodson, as applied to claim 1 above, and further in view of EP 0623354 (“Berg”).

Claim 13 recites: “wherein the fluid is of a type to physically entrap the impurity without dissolving the impurity.” As indicated above for claim 1, Buchanan, Inoue, Hughes, and Goodson individually and when combined, fail to teach or suggest this limitation of claim 13. Berg fails to cure this deficiency of Buchanan, Inoue, and Hughes. Accordingly, Applicant respectfully submits that claim 13 is patentably allowable over the cited references.

Claims 16-18 and 36-37 depend from claim 13 and are patentably allowable over the cited references for at least the same reasons as claim 13.

5. Claims 23-27 and 29 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Buchanan, Inoue, Hughes and Goodson, as applied to claim 1 and further in view of US Publication 2001/0009656 (Greff et al.) and U.S. Publication 2002/0031616 (Neoh et al.).

Claim 23 recites “the fluid is selected from the group consisting of FLUX REMOVER AMS, dimethyl acetamide, dimethyl formamide, cyclohexane, dimethyl sulfoxide, and combinations thereof.” Applicants respectfully disagree that the limitations of claim 1 apply to claim 23 as asserted by the Examiner. Claim 23 is an independent claim.

Neoh et al. is directed to a method of preparing an electrically conductive polymeric material. Although Neoh et al. discloses that dimethyl-formamide (DMF) may remove unreacted monomer and homopolymer, there is no indication that this material will be introduced into a living being, and thus would be safe for use in medical devices, such as stents. Thus, one of skill in the art would not likely look to Neoh et al., in a totally unrelated field, to solve the problem of removing unreacted monomers. Additionally, as indicated in the attached sheet 24305 from the Federal Register, DMF is a Class 2 Solvent and not a Class 3 Solvent as alleged by the Examiner in the next section. Class 2 solvents are classified as “Solvents to be limited – Nongenotoxic animal carcinogens or possible causative agents of other irreversible toxicity such as neurotoxicity or teratogenicity” on page 24303. Thus, one of skill in the art would be even less likely to use DMF as a solvent because it does not have a Class 3 rating, which is less toxic and of lower risk to human health. Therefore, the cited references fail to suggest the above limitation of claim 23 such that one of ordinary skill in the art would be motivated to use it. Accordingly, Applicants respectfully submit that claim 23 is patentably allowable over the cited references.

Claims 24-27 and 29 depend from claim 23 and are patentably allowable for at least the same reason as claim 23.

6. Claims 23-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan, Inoue, Hughes and Goodson, as applied to claim 1 and further in view of US Publication 2001/0000230 (Bernstein et al).

Claim 23 recites “the fluid is selected from the group consisting of FLUX REMOVER AMS, dimethyl acetamide, dimethyl formamide, cyclohexane, dimethyl sulfoxide, and combinations thereof.” The cited references fail to teach or suggest this limitation of claim 23.

Specifically, the Examiner asserts that Bernstein et al. teaches that DMF is rated as a Class 3 residual solvent by the FDA. This is not the case as evidenced by the attached page from the Federal Register, Vol. 62, No. 85, page 24305 (May 1997) classifying DMF as a Class 2 solvent. Class 2 solvents are classified as “Solvents to be limited – Nongenotoxic animal carcinogens or possible causative agents of other irreversible toxicity such as neurotoxicity or teratogenicity” on page 24303. Thus, one of skill in the art would not likely be inclined to use DMF as a solvent because it does not have a Class 3 rating, which is less toxic and of lower risk to human health. Thus, the cited references fail to suggest the above limitation of claim 23 such that one of ordinary skill in the art would be motivated to use it. Accordingly, Applicants respectfully submit that claim 23 is patentably allowable over the cited references.

Claims 24-27 and 29 depend from claim 23 and are patentably allowable for at least the same reason as claim 23.

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CONCLUSION

In light of the foregoing remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

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